DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 17, 2015

Signature Orthopaedics Pty Ltd.
Dr. Declan Brazil
Managing Director
7 Sirius Road
Lane Cove, NSW 2066
Australia

Re: K143184
Trade/Device Name: Evolve™ UniPolar Head
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWL
Dated: February 9, 2015
Received: February 11, 2015

Dear Dr. Brazil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 INDICATIONS FOR USE STATEMENT

510(k) Number (if Known): K143184

Device Name: Evolve™ UniPolar Head

Indications For Use:

Signature Orthopaedics' Evolve UniPolar Head is intended for hemi-hip arthroplasty only, where the natural acetabulum does not require replacement. The Evolve UniPolar Head is indicated for bone fractures or pathologies involving only the femoral head/neck and/or proximal femur, such as:

- Acute femoral head or neck fracture
- Fracture dislocation of the hip
- Avascular necrosis of the femoral head
- Non-union of femoral neck fractures
- Certain high subcapital and femoral neck fractures in the elderly
- Degenerative arthritis involving only the femoral head

Prescription Use: Yes (Part 29 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: No (Part 29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Signature Orthopaedics Pty Ltd

2 510(K) SUMMARY

Manufacturer: Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Australia

Device Trade Name: Evolve™ UniPolar Head

Common Name: Hip Prosthesis

Contact: Dr. Declan Brazil
Managing Director

Prepared By: Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Australia
Phone: +61 (2) 9428 5181
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Date Prepared: October 21st, 2014

Classification: Class II per 21 CFR 888.3360: Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)

Predicate Devices: Substantial equivalence to the following devices is claimed:

- Signature Orthopaedics Origin Total Hip System CoCr Femoral Head (K121297)
- Signature Orthopaedics BiPolar Head (K133370)
- Smith & Nephew Tandem UniPolar Head (K896580)
- Global Manufacturing Technology MSA Hip System (K102172)

Device Description:

The Evolve™ UniPolar Head is a metallic (per ISO 5832-12) ball with a tapered bore. The head connects to a femoral stem from Signature Orthopaedics' range via taper sleeve. The taper sleeve is manufactured from cobalt-chromium alloy per ISO 5832-12, and includes a 12/14 taper. The head's outer surface is highly polished to articulate against the patient's natural acetabulum as part of a hip hemi-arthroplasty.

Indications for Use:

Signature Orthopaedics' Evolve UniPolar Head is intended for hemi-hip arthroplasty only, where the natural acetabulum does not require replacement. The Evolve UniPolar Head is indicated for bone fractures or pathologies involving only the femoral head/neck and/or proximal femur, such as:

- Acute femoral head or neck fracture

- Fracture dislocation of the hip
- Avascular necrosis of the femoral head
- Non-union of femoral neck fractures
- Certain high subcapital and femoral neck fractures in the elderly
- Degenerative arthritis involving only the femoral head

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Evolve™ UniPolar Head is adequate for anticipated in-vivo use. Non-clinical testing included:

- Range of motion analysis
- Component connection strength and fretting corrosion testing
- Femoral stem fatigue testing

Substantial Equivalence:

The Evolve UniPolar Head's design is similar to the Signature Orthopaedics CoCr Femoral Head (K121297), including articular surface and taper connection geometry, to allow use with Signature Orthopaedics existing femoral stem range. The Evolve UniPolar Head's design and intended use are similar to the Signature Orthopaedics BiPolar Head (K133370) and Smith & Nephew Tandem UniPolar Head (K896580). Non-clinical testing results support the substantial equivalence claim. The Evolve UniPolar Head is expected to perform adequately during clinical use.